

REMARKS

Claims 1-3, 17-19, 23-25 and 29 are currently pending in the present application. In the outstanding Office Action, the Examiner rejected claims 1-3, 17-19, 23-25 and 29 under 5 35 U.S.C. §101 as allegedly lacking patentable utility. The Examiner also rejected claims 1-3, 17-19, 23-25 and 29 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement on the basis that one of ordinary skill in the art would not know how to use the claimed invention. The Examiner also separately rejected claims 1-3, 17-19, 23-25 and 29 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was 10 not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. The Examiner also rejected claims 1-3, 17-19, 23-25 and 29 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention.

The present invention has been described in Applicants' prior response, 15 incorporated by reference herein.

FORMAL REJECTIONS

As mentioned above, the Examiner rejected claims 1-3, 17-19, 23-25 and 29 under 35 U.S.C. §101 as allegedly lacking patentable utility. In the Office Action, page 3, 2<sup>nd</sup> 20 paragraph, the Examiner stated that "there is no recited utility for a uniform distribution of data from random gene expression signals of unknown origin, as recited in the instant claims." Applicants respectfully disagree with the Examiner's above conclusion and characterization of the present claims. First, independent claims 1/17/23, from which claims 2, 3, 29/18, 19/24, 25, respectively depend, recite, in part, transforming gene expression signals into a uniform 25 distribution of transformed gene expression signals that may be used to determine gene expression patterns. Therefore, there is a clearly recited use for a uniform distribution of transformed gene expression signals, namely that of determining gene expression patterns. The Examiner's statements, provided above and as will be presented below, in no way negate this point.

Applicants again respectfully point out that M.P.E.P. §2107 II. (A)(3) states that,

[a]n invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible.

M.P.E.P. §2107 II. (B) (1) states that,

[i]f the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a ‘specific and substantial utility’) and the assertion would be considered credible by a person of ordinary skill in the art, [a rejection based on lack of utility] should not be imposed]. (emphasis added)

Independent claims 1/17/23 clearly set forth a practical purpose, that of determining gene expression patterns. Therefore, for at least that reason Applicants respectfully submit that the rejection of claims 1-3, 17-19, 23-25 and 29 under 35 U.S.C. §101 should be withdrawn.

The Examiner further stated, on page 3, 2<sup>nd</sup> paragraph, of the Office Action, that,

It is acknowledged that the specification provides utility for the transformation of gene expression signals from controls (healthy individuals) and transformation of gene expression signals from a phenotype set (unhealthy individuals) that are then both used for comparison of expression levels between the two sets. However, the instant claims do not recite such steps of transformation of healthy and unhealthy gene expression signals that are then compared to assess differences or similarities in the expression levels. There is no immediate benefit provided for the transformation of a single set of gene expression signals of unknown origin. And therefore, the instant claims lack utility.

The Examiner also stated, on page 3, 3<sup>rd</sup> paragraph, of the Office Action, that,

There is neither recitation of a statistically significant pattern found in a phenotype set, nor comparison to determine membership in a phenotype or a control set. For these reasons, the claims lack utility.

Arguably, the invention as claimed in claims 1-3, 17-19, 23-25 and 29 has utility by virtue of the fact that the uniform distribution of gene expression signals obtained therefrom can be used to determine maximal patterns, or gene expression patterns that can be used as part

of a discriminant function to perform actions similar to those alluded to by the Examiner, e.g., examine sample vectors (see, for example, page 9, lines 13-25, of the specification). Viewed another way, without performing the claimed techniques, actions, such as finding gene expression patterns and using them to classify sample vectors, would be markedly more difficult to perform. Therefore, claims 1-3, 17-19, 23-25 and 29 must possess utility.

Given the above remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-3, 17-19, 23-25 and 29 under 35 U.S.C. §101.

As mentioned above, the Examiner also rejected claims 1-3, 17-19, 23-25 and 29 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement on the basis that one of ordinary skill in the art would not know how to use the claimed invention. Specifically, in the Office Action, page 4, 2<sup>nd</sup> paragraph, the Examiner stated that,

Applicant [in the previous response] argues that one would know how to make and use the invention. This is not persuasive. Normalization of a random set of gene expression signals without the comparison outlined in the specification . . . does not teach one of skill in the art how to use the said invention. How does one make a comparison with just one set of random transformed expression signals?

Applicants respectfully submit that the Examiner has misunderstood the present teachings. Applicants are not certain what the Examiner is referring to by the phrase “random set of gene expression signals.” Nowhere do any of claims 1-3, 17-19, 23-25 and 29, nor the supporting specification, mention a random set of signals. Further, Applicants do not understand how “the comparison” the Examiner is referring to has anything to do with enabling one of ordinary skill in the art to practice the claimed invention.

Independent claims 1/17/23 recite, in part, that a transformation is used to transform a plurality of gene expression signals for a gene into transformed gene expression signals for the gene, resulting in a uniform distribution of the transformed gene expression signals. By way of example only, beginning on page 14, line 9, of the specification, it is described that transformations are used to take probability density distributions for columns of a control matrix and transform them to a uniform probability density. As Applicants pointed out in

their previous response, an exemplary transformation  $f_g$  is shown on page 13, line 16, of the specification. These teachings in the specification, in conjunction with the teachings of the claims, clearly would enable one of ordinary skill in the art to practice the claimed invention.

According to M.P.E.P. §2164.01 “[a]ny analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention.” The teachings of the present specification, e.g., as in the referenced section, clearly set forth how to use a transformation to transform a plurality of gene expression signals for a gene into transformed gene expression signals for the gene, resulting in a uniform distribution of the transformed gene expression signals.

It is unclear what “the comparison” the Examiner is referring to has to do with enabling one of ordinary skill in the art to practice the claimed invention, e.g., to use a transformation to transform a plurality of gene expression signals for a gene into transformed gene expression signals for the gene, resulting in a uniform distribution of the transformed gene expression signals. A comparison is not claimed. Notwithstanding, the Examiner stated that “the comparison” is “outlined in the specification” (see above) and therefore, regardless of its applicability to the claimed invention, by the Examiner’s own admissions, it is enabled by the specification.

Given the above remarks, Applicants respectfully request reconsideration and withdrawal of the rejections of claims 1-3, 17-19, 23-25 and 29 under 35 U.S.C. §112, first paragraph.

As mentioned above, the Examiner also rejected claims 1-3, 17-19, 23-25 and 29 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. Specifically, on page 5, 2<sup>nd</sup> paragraph, of the Office Action, the Examiner stated that,

without a recitation of a comparison step using two different sets of gene expression signals from different sample [sic.] or tissues, etc. one of skill

in the art would not have known how to **use** the instant invention and therefore, the claims lack enablement.

First, Applicants are not certain how these rejections differ from the rejections under 35 U.S.C. §112, first paragraph, addressed immediately above. However, Applicants also fail to see the relevance of a comparison step, as alleged by the Examiner, in enabling a person of skill in the art to use the invention. As highlighted above, Independent claims 1/17/23 recite, in part, that a transformation is used to transform a plurality of gene expression signals for a gene into transformed gene expression signals for the gene, resulting in a uniform distribution of the transformed gene expression signals. These steps are clearly supported by the specification, by way of example only, in conjunction with the gene expression signals for a control matrix. See, for example, the specification beginning on page 14, line 9, wherein it is described that transformations are used to take probability density distributions for columns of a control matrix and transform them to a uniform probability density.

As stated above, these teachings in the specification clearly would enable one of ordinary skill in the art to practice the claimed invention. As such, Applicants respectfully request reconsideration and withdrawal of the rejections.

As mentioned above, the Examiner also rejected claims 1-3, 17-19, 23-25 and 29 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Specifically, the Examiner stated beginning on page 5, 5<sup>th</sup> paragraph, of the Office Action, that,

Claim 1 recites ‘deriving a transformation that transforms the plurality of gene expression signals into transformed gene expression signals for the gene, resulting in a uniform distribution of the transformed gene expression signals within a selected interval. . . .’ It remains unclear whether or not this step is intended to transform a gene expression signal into a uniform distribution so that the uniform distribution is used to somehow detect gene expression patterns. The Examiner contends that this series of steps is circular in nature.

Applicants respectfully disagree with the Examiner. The steps recited in independent claims 1/17/23 are not circular. Basically, the transformation transforms gene expression signals into transformed gene expression signals, resulting in a uniform distribution

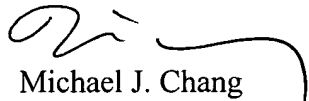
of transformed gene expression signals. The uniform distribution of transformed gene expression signals (whose distribution after transformation is uniform) may be used to determine gene expression patterns. It is Applicants' position that the above claim language is sufficiently descriptive and would be clear to one of ordinary skill in the art.

5                In view of the foregoing, Applicants submit that all of the pending claims, i.e., claims 1-3, 17-19, 23-25 and 29, are in condition for allowance and such favorable action is earnestly solicited.

              If any outstanding issues remain, or if the Examiner has any further suggestions for expediting allowance of this application, the Examiner is invited to contact the undersigned at  
10    the telephone number indicated below.

              The Examiner's attention to this matter is appreciated.

Respectfully submitted,



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